BeneHeart R12/BeneHeart R12A Electrocardiograph

Service Manual

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this product and this manual. This manual may refer to information protected by copyrights or patents and does not convey any license under the patent rights of Mindray, nor the rights of others. Mindray does not assume any liability arising out of any infringements of patents or other rights of third parties.

mindray, MINDRAY, and MINDRAY are the registered trademarks or trademarks owned by Mindray in China and other countries.

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

- Version number 1.0
- Release time: December 2013

© 2013 Shenzhen Mindray Bio-Medical Electronics Co., Ltd. All rights reserved.

Preface

Manual Purpose

This manual provides detailed information about the assembling, dissembling, testing and troubleshooting of the equipment to support effective troubleshooting and repair. It is not intended to be a comprehensive, in-depth explanation of the product architecture or technical implementation. Observance of the manual is a prerequisite for proper equipment maintenance and prevents equipment damage and personnel injury.

Intended Audience

This manual is for biomedical engineers, authorized technicians or service representatives responsible for troubleshooting, repairing and maintaining the equipment.

Contents

1 General 1-1

1.1 Revision History 1-1

1.2 Safety Information 1-2

1.2.1 Warnings 1-2

1.2.2 Cautions 1-3

1.2.3 Notes 1-3

1.3 Equipment Symbols 1-4

2 Theory of Operation 2-1

2.1 Introduction 2-1

2.2 Device Connector 2-2

2.2.1 Back View 2-2

2.3 Main Unit 2-3

2.3.1 Top Cover Assembly 2-4

2.3.2 Middle Frame Assembly 2-4

3 Unpacking and Installation 3-1

3.1 Unpacking the Equipment 3-1

3.2 Preparation for Installation 3-1

3.2.1 Environmental Requirements 3-1

3.2.2 Checking Paper Tray Size 3-2

3.3 Turning On the Equipment 3-2

4 Hardware and Software Upgrade 4-1

4.1 Hardware Upgrade 4-1

4.1.1 Upgrading the Equipment to have Wi-Fi Function 4-1

4.2 Software Upgrade 4-1

4.2.1 Installing Software Upgrade Tool 4-2

4.2.2 Software Upgrade Procedure 4-4

5 Testing and Maintenance 5-1

5.1 Introduction 5-1

5.1.1 Testing Tool 5-1

5.1.2 Test Report 5-1

5.1.3 Preventative Maintenance 5-1

5.1.4 Recommended Frequency 5-2

5.2 Visual Inspection 5-2

5.3 Power-on Test 5-2

5.4 ECG Performance Test 5-3

5.5 Battery Check 5-3

5.6 Factory Maintenance 5-4

5.7 Electrical Safety Tests 5-4

6 Troubleshooting 6-1
6.1 Overview 6-1
6.2 Parts Replacement 6-1
6.3 General Problems and Prompts 6-1
6.4 Troubleshooting Guide 6-2
6.4.1 Power On/Off Failure 6-2
6.4.2 Recorder Failure 6-2
6.4.3 Wrong System Time 6-3

7 Disassembly and Repair 7-1
7.1 Tools Required 7-1
7.2 Preparations for Disassembly 7-1
7.3 Disassembling the Main Unit 7-2
7.3.1 Removing the Battery 7-2
7.3.2 Removing Bottom Case Assembly 7-2
7.3.3 Removing the Top Cover FRU 7-3
7.3.4 Removing the M502 USB Interface PCBA 7-4
7.3.5 Removing the Speaker 7-4
7.3.6 Removing the AC-DC Module 7-5
7.3.7 Removing the Power Management and Interface Board PCBA 7-5
7.3.8 Removing the ECG Board (FRU) 7-6
7.3.9 Removing the Battery Interface Board PCBA 7-6
7.3.10 Removing the Main Board FRU 7-7
7.3.11 Removing the Thermal Print Head 7-7
7.3.12 Removing the Button Board 7-7
7.3.13 Replacing the Power Button and Function Buttons 7-8
7.3.14 Removing the LCD 7-8
7.3.15 Removing the Top Cover FRU 7-8

8 Parts 8-1
8.1 Introduction 8-1
8.2 Main Unit 8-2
8.2.1 Exploded View 8-2
8.2.2 Parts List 8-2
8.3 Upper Housing Assembly 8-3
8.3.1 Exploded View 8-3
8.3.2 Parts List 8-3
8.4 Middle Frame Assembly （115-022702-00） 8-5
8.4.1 Exploded View 8-5
8.4.2 Parts List 8-5
8.5 Bottom Case Assembly （115-022703-00） 8-7
8.5.1 Exploded View 8-7
8.5.2 Parts List 8-7

9 Replaceable Parts and Upgrade Packages 9-1
9.1 Replaceable Parts and Upgrade Packages 9-1

9.2 Parts Change List....9-2

A Electrical Safety Inspection A-1

A.1 Power Cord Plug.... A-1

A.2 Device Enclosure and Accessories.... A-2

A.3 Device Labeling.... A-2

A.4 Protective Earth Resistance.... A-2

A.5 Earth Leakage Test.... A-4

A.6 Patient Leakage Current.... A-5

A.7 Mains on Applied Part Leakage.... A-7

A.8 Patient Auxiliary Current.... A-9

A.9 Scheduled Electrical Safety Inspection....A-10

A.10 Electrical Safety Inspection after Repair A-11

FOR YOUR NOTES

1 General

1.1 Revision History

Manual Version	Description of Changes	Revision Time	SN Since
1.0	First release	December 2013	

1.2 Safety Information

⚠WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.2.1 Warnings

⚠WARNING

- **All installation operations, expansions, changes, modifications and repairs of this product are conducted by authorized personnel.**
- **Disconnect the equipment from external power source and remove the battery before disassembling the equipment.**
- **When you disassemble/reassemble the equipment, a patient leakage current test must be performed before it is put in use.**
- **The equipment must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on battery power, if possible.**
- **Dispose of the package material, observing the applicable waste control regulations and keeping it out of children's reach.**

1.2.2 Cautions

⚠CAUTION

- **Make sure that no electromagnetic radiation interferes with the performance of the equipment when preparing to carry out performance tests. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Protect the equipment from damage caused by drop, impact, strong vibration or other mechanical force during servicing.**

1.2.3 Notes

NOTE

- **Refer to Operation Manual for detailed operation and other information.**

1.3 Equipment Symbols

	Equipotentiality		Analog out
	Network connector		USB connector
	Telephone line connector		ON/OFF for part of equipment
	Battery indicator		Alternating current (AC)
	Caution		Refer to instruction manual/ booklet
	DEFIBRILLATION-PROOF TYPE CF APPLIED PART		Serial number
	Warning; Electricity		ESD warning symbol for electrostatic sensitive devices.
	Manufacturer		DATE OF MANUAFACTURE
	Dispose of in accordance to your country's requirements		Environment-friendly Used Period per Chinese Standard SJ/T11363-2006
	China Metrology Certification		Authorized representative in the European Community
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.		

NOTE

- **Some symbols may not appear on your equipment.**

2 Theory of Operation

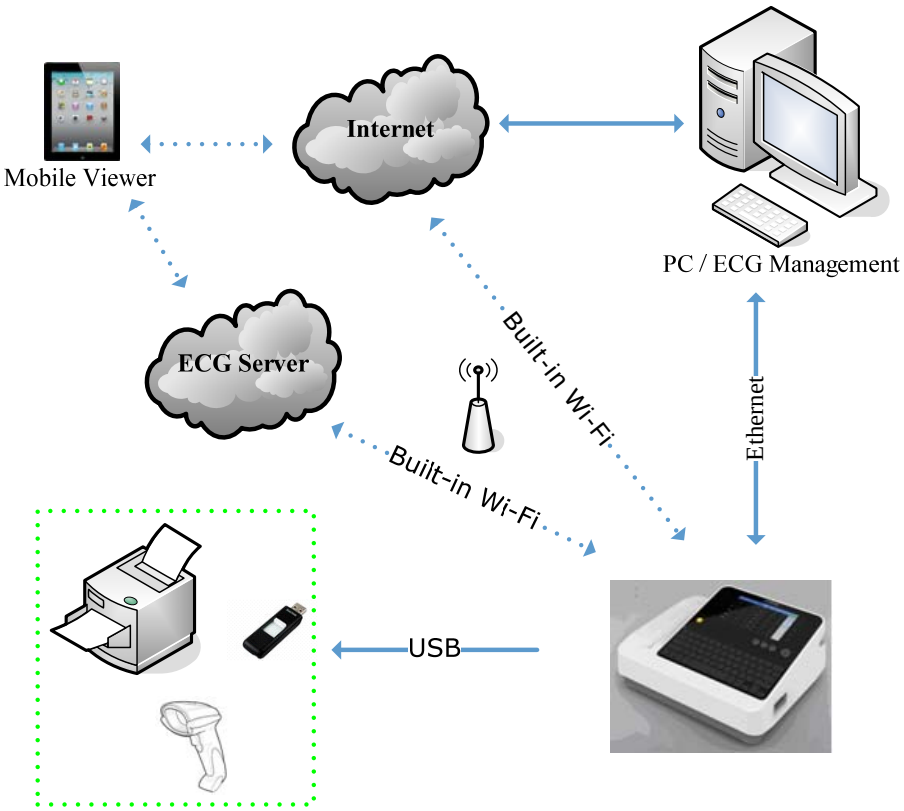
2.1 Introduction

BeneHeart R12/BeneHeart R12A electrocardiographs (hereafter referred to as "the equipment" or "the system") are intended to acquire, analyze, display, store, and record electrocardiographic information for adult and children of any age from birth upwards for clinical diagnosis and study.

The equipment can be used to:

- Acquire, analyze, displays, and record 12-lead ECG information.
- Provide ECG algorithm to automatically analyze the acquired ECG waveforms; output measurements and diagnosis.
- Support auto measurement, manual measurement, and rhythm measurement.
- Print ECG reports through either an internal thermal recorder or an external printer.
- Store, preview, and review ECG reports.
- Connect LAN or Wi-Fi to send ECG data.
- Support entering patient information through the keyboard or a barcode reader.
- Present messages in case of lead off, interference, low battery, or other abnormity.

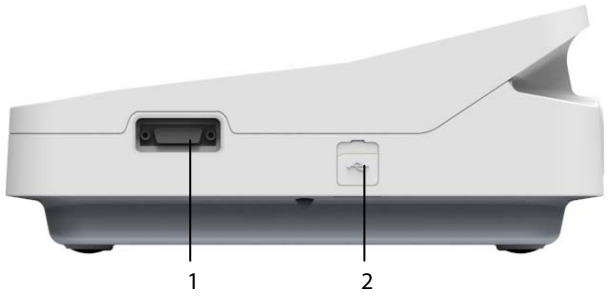
The following picture shows the electrocardiograph and the external devices.



2.2 Device Connector

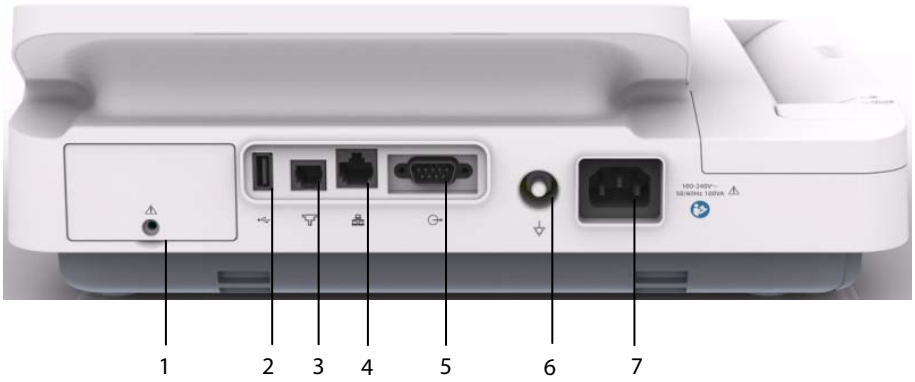
All the connectors are located at the right side or at the rear, see the pictures below.

Right View



1. Patient cable connector: connects the patient cable for ECG acquisition.
2. USB connector: connects USB devices, such as a USB drive, external printer, or barcode reader.

2.2.1 Back View



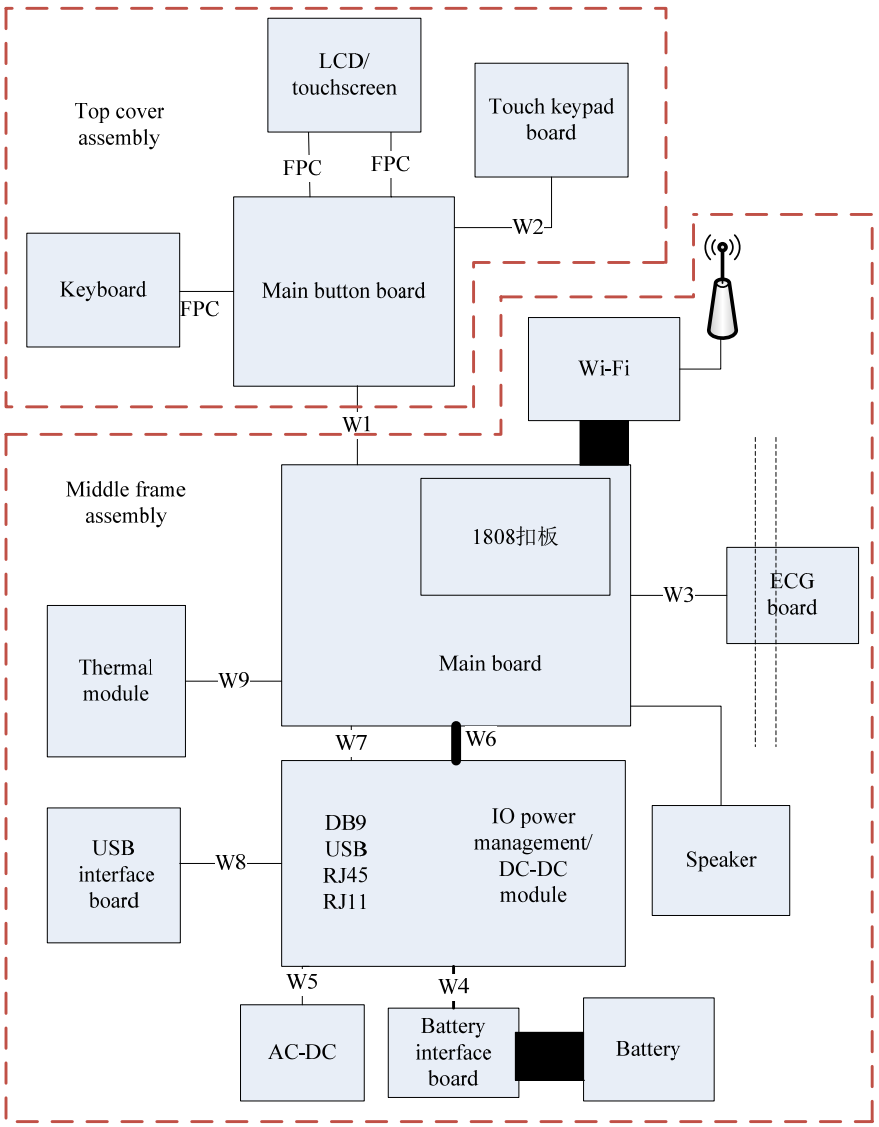
1. Battery compartment
2. USB connector: connects USB devices, such as a USB drive, external printer, or barcode reader.
3. Telephone line connector: for future external devices. Do not use.
4. Network connector: a standard RJ45 connector for software upgrade and sending ECG data.
5. Analog output connector: for future external devices. Do not use.
6. Equipotential Grounding Terminal: when using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential differences between them.
7. AC power input: connects the power cord to run the equipment on AC power supply.

2.3 Main Unit

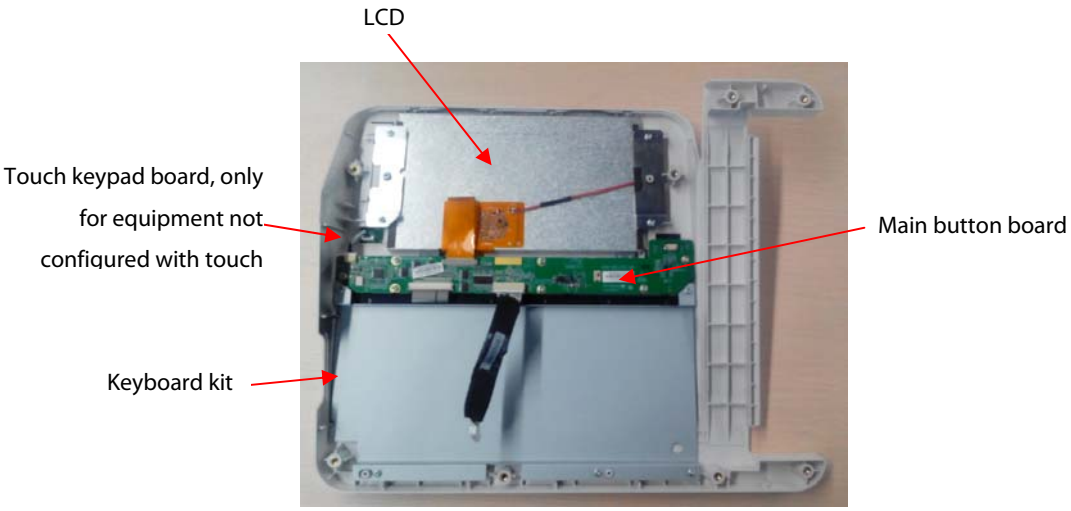
The electrocardiograph consists of the following assemblies:

- Top cover assembly: consists of major button board, display, touchpad board (only for the equipment not configuring a touchscreen), and keyboard kit.
- Middle frame assembly : consists of main board (including the mother board and the daught board), thermal module, USB adapting board, speaker, power management board, ECG board, battery interface board, and AC-DC module.
- Lower cover assembly : is the paper tray assembly.

The following picture shows the architecture of the main unit.



2.3.1 Top Cover Assembly



Main button board

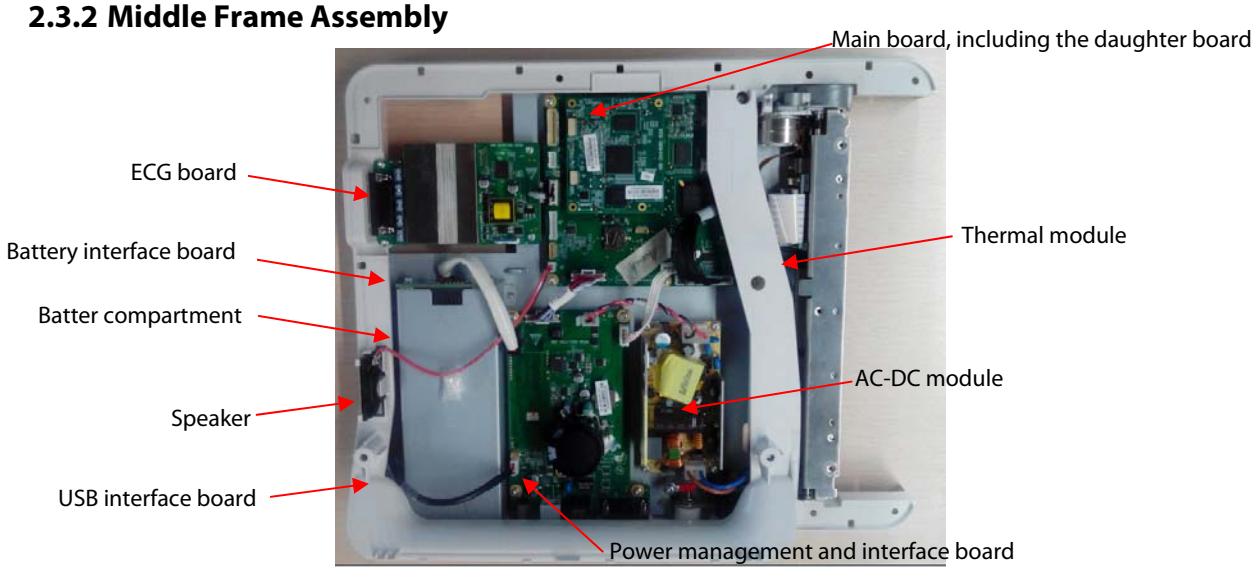
Consists of the following circuits:

- Button scanning circuit
- Display signal level switching circuit (LVDS level to TTL level)
- LCD backlight creation circuit
- Touch button signal transmission circuit
- Touchscreen drive circuit
- Power switch and power indicator circuit

Touch keyboard

Drives touch button and backlight.

2.3.2 Middle Frame Assembly



AC/DC module

Converts AC power into DC power.

Power management and interface board

Consists of the following circuits:

- Voltage conversion circuit to output 24 V power for recorder module and 5 V power for main board
- Power management module circuit
- Battery charging circuit
- IO circuit

ECG board

Acquires the patient's ECG signal.

Main board

Runs system software, drive thermal module, runs data storage and some parameter software, including the Glasgow algorithm and filter algorithm.

Battery interface board

Adapts the battery connector and the battery management board.

USB interface board

Drives USB connector.

FOR YOUR NOTES

3 Unpacking and Installation

3.1 Unpacking the Equipment

Open the package and take out the packing list. Check that all the articles included in the packing list are available and the quantity and specification are correct.

- All the optional parts purchased by the customer shall also be checked.
- Notify the supplier if provided components are not correct as compared to the packing list.
- In case of damage during transportation, keep the packing material and notify the supplier immediately.
- Keep the packing material till the equipment is accepted.

3.2 Preparation for Installation

1. Ensure that the site meets all safety, environmental and power requirements
2. Check that required power sockets are available.
3. Check that a network connector is available if the equipment needs to be connected to the wired network.

3.2.1 Environmental Requirements

To avoid explosion hazard, do not use the equipment in the presence of flammable anaesthetics, vapours or liquids. The environment where the equipment will be used should be reasonably free from vibration, dust and corrosive substances. If these conditions are not met, the accuracy of the system may be affected and damage may occur.

Environment

Check and make sure that there is no electromagnetic interference source around the equipment, especially large medical electrical equipment such as radiological equipment and magnetic resonance imaging equipment etc. Switch off these devices when necessary. Keep the examination room warm (no less than 18℃) to avoid muscle action voltages in ECG signal caused by cold.

Power supply

Check that power supply specification is met and the power cord is securely connected if mains power is used. Use only power socket that is properly grounded.

The power supply specifications are as follows:

AC mains	
Input voltage	100-240V～ (±10%)
Input power	100 VA
Frequency	50 Hz/60 Hz (±3 Hz)
Battery	
Battery Type	Rechargeable lithium-ion battery, 4500 mAh, 11.1 V
Run time	For equipment in standard configure and with default setting, when powered by a new fully-charged battery and at ambient temperature 25 ºC±5 ºC: ≥400 auto reports, or no less than one hour of continuous paper recording, or no less than 3.5 hours of paperless recording
Charge time	With the equipment power off: ≤6 h to 90% capacity ≤7 h to 100% capacity
Shutdown delay	at least 5 minutes (after a low battery message first occurs)

3.2.2 Checking Paper Tray Size

The equipment can print either on A4 (295 mm × 210 mm) or US Letter (8.5″ × 11″) paper. Before installing the equipment, check if the paper tray size is ok.

To change the paper size, move the white plastic spacer bar in the paper tray to limit the paper tray.

- For A4 sized paper, insert the spacer in the slot at the top of the paper tray.
- For US Letter sized paper, insert the spacer in the slot at the bottom of the paper tray.

Check that the paper tray is configured to meet the appropriate paper size for the destination location.

3.3 Turning On the Equipment

Once the equipment has been installed and checked, you can get ready for measurement and recording:

1. Connect the equipment with AC mains. If you run the equipment on battery power, ensure that the battery is sufficiently charged.
2. Press the Power switch.

4 Hardware and Software Upgrade

4.1 Hardware Upgrade

4.1.1 Upgrading the Equipment to have Wi-Fi Function

For the equipment not configured with the Wi-Fi function, there is no Wi-Fi module socket on the main board. To upgrade the equipment, use a main board with Wi-Fi module socket to replace the original main board.

The Glasgow 12-lead resting ECG algorithm and the PDF software package are included in the Wi-Fi upgrade package.

The Wi-Fi upgrade package (PN: 115-022979-00) consists of the following items:

- Main board PCBA, with Wi-Fi module socket
- Wi-Fi module kit
- System software package
- Glasgow 12-lead resting ECG algorithm
- PDF software package

4.2 Software Upgrade

You can upgrade the system by installing and running the ***Mindray Patient Monitor Software Upgrade Tool (PN: 110-000493-00)*** on a PC with Windows operating system.

Connect the equipment to be upgraded and the PC running the upgrade tool to the same network, or directly connect the equipment and the PC via a crossover network cable. Then configure the IP address of the PC. You can upgrade the following software:

No.	Software type	PN	Description	Remark
1	System related software	110-002925-00	System software	/
2		110-002926-00	Language library	
3		110-002927-00	Icon library	
4	FPGA logic	110-002805-00	Main board chip writing software	
5	LINUX platform software	110-002924-00	Linux kernel, including the drive	
6	PDF grid software	110-002929-00	PDF grid software	
7	EEPROM mirror file	110-002928-00	EEPROM configuration software	

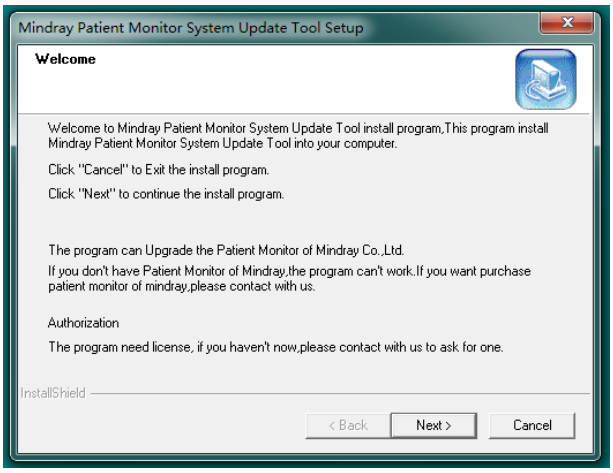
No.	Software type	PN	Description	Remark
8	Glasgow ECG configuration file	110-002930-00	Glasgow 12-lead resting ECG algorithm	Download as per the purchase order
9	PDF configuration file	110-002940-00	PDF configuration package	Download as per the purchase order

NOTE

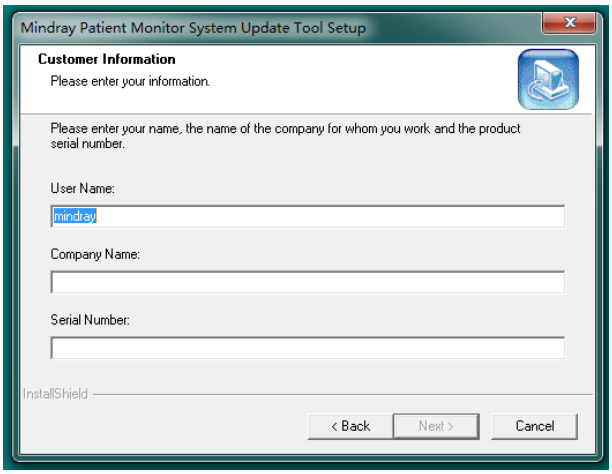
- **No specific sequence is required when upgrading above software. For detailed information, please refer to 4.2.2 Software Upgrade Procedure.**

4.2.1 Installing Software Upgrade Tool

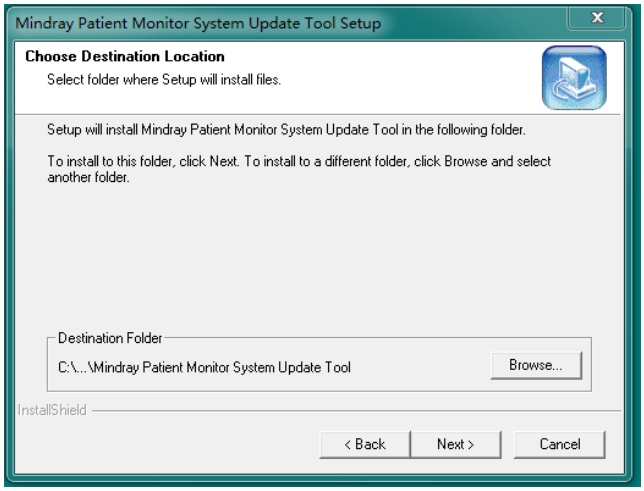
1. Find the installation program SystemUpdateTool.exe, and double click it to start installation.
2. Select language.3. Click [**Ok**] and the following screen is displayed. Click [**Next**] to go to the next step.


Mindray Patient Monitor System Update Tool Setup
Welcome
Welcome to Mindray Patient Monitor System Update Tool install program,This program install Mindray Patient Monitor System Update Tool into your computer.
Click "Cancel" to Exit the install program.
Click "Next" to continue the install program.
The program can Upgrade the Patient Monitor of Mindray Co.,Ltd.
If you don't have Patient Monitor of Mindray,the program can't work.If you want purchase patient monitor of mindray,please contact with us.
Authorization
The program need license, if you haven't now,please contact with us to ask for one.
InstallShield
< Back
Next >
Cancel

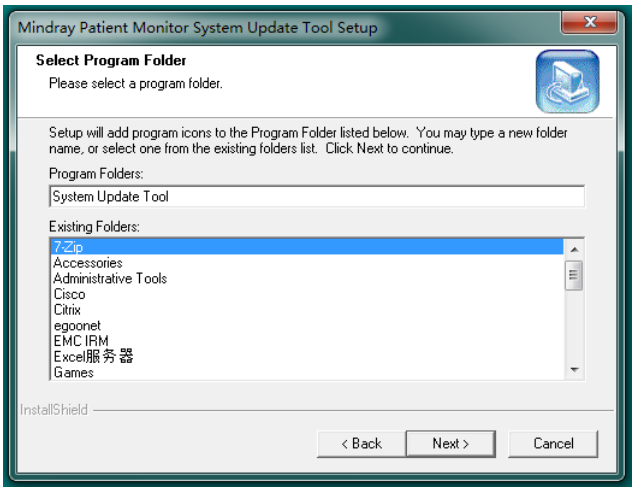
4. Enter User Name, Company name, and the Serial Number 26582640. Then click [**Next**].


Mindray Patient Monitor System Update Tool Setup
Customer Information
Please enter your information.
Please enter your name, the name of the company for whom you work and the product serial number.
User Name:
mindray
Company Name:
Serial Number:
InstallShield
< Back
Next >
Cancel

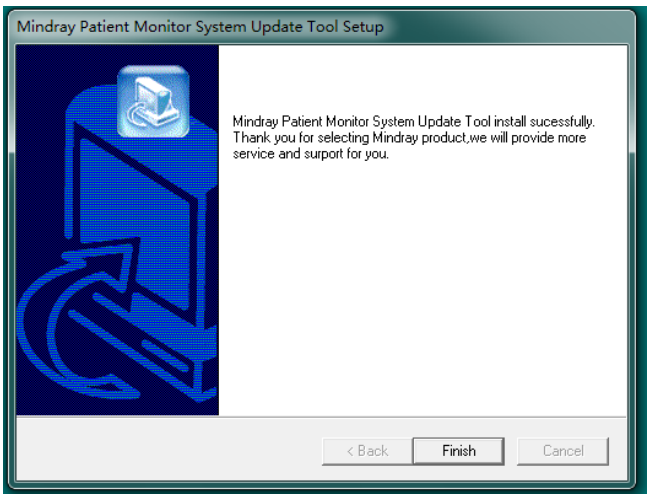
5. Specify the destination folder for installing this program. Then select [**Next**].


Mindray Patient Monitor System Update Tool Setup
Choose Destination Location
Select folder where Setup will install files.
Setup will install Mindray Patient Monitor System Update Tool in the following folder.
To install to this folder, click Next. To install to a different folder, click Browse and select another folder.
Destination Folder
C:\...\Mindray Patient Monitor System Update Tool
Browse...
InstallShield
< Back
Next >
Cancel

6. Select Program Folder. Then select [**Next**].



7. Click [**Finish**] to complete installation.

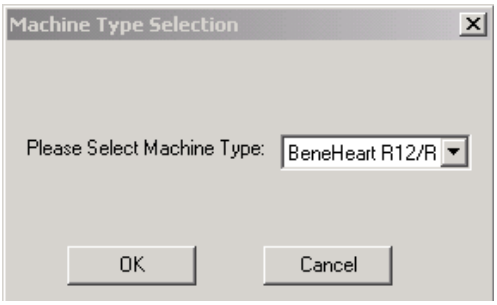

Mindray Patient Monitor System Update Tool Setup
Mindray Patient Monitor System Update Tool install sucessfully.
Thank you for selecting Mindray product,we will provide more service and surport for you.
< Back
Finish
Cancel

4.2.2 Software Upgrade Procedure

Before software upgrade, check the current software version. The software version is recorded on the bottom of the printed report. You can also check software version by entering factory maintenance. Refer to ***5.6 Factory Maintenance***.

To upgrade the software:

1. Connect the equipment to be upgraded and the PC running the upgrade tool to the same network, or directly connect the equipment and the PC via a crossover network cable.
2. On the electrocardiograph, press the [Setup] key to enter the main menu. Select [**Maintenance**] →[**Network Type**]. Set [**Network Type**] to [**LAN**].
3. Set the IP address of the PC to "77.77.1.XX" and subnet mask to "255.255.255.0".
4. Run Mindray Patient Monitor Software Upgrade Tool on the PC and set Machine to [**BeneHeart R12/R12A**].



5. On the Mindray Patient Monitor Software Upgrade Tool screen, select [**Select Package**] and then the packages you want to upgrade. Then select [**Start**].
6. Turn on the equipment to be upgraded. Press and hold the "Ctrl" key and the "B" key for 2 to 3 seconds. Then the equipment enters the upgrade mode and starts software upgrade automatically.

   The upgrade progress is displayed on both the electrocardiograph and the PC. Software upgraded finishes when the Upgrade Tool screen displays “System upgraded successfully”.
7. Restart the equipment and check the current software version to verify if the software is correctly upgraded.

⚠CAUTION

- **Disconnect the equipment from the patient and make sure the important data are saved before upgrade.**
- **Do not shut down or power off the equipment when upgrading the system software. Otherwise, it may cause the equipment to break down.**
- **Software upgrade should be performed by qualified service personnel only.**
- **Crossover network cable is recommended when a PC is connected for software upgrade.**

NOTE

- **Make sure the version of the upgrade package is what you desired. To obtain the latest upgrade package, please contact Mindray Customer Service Department.**

5 Testing and Maintenance

5.1 Introduction

To ensure the equipment always functions normally, refer regular inspection, maintenance, and test to qualified service personnel. This chapter provides a checklist of the testing procedures with recommended testing tools and frequency. The service personnel should perform the testing and maintenance procedures as required and use appropriate testing tools.

The testing procedures provided in this chapter are intended to verify that the equipment meets the performance specifications. If the equipment or a module fails to perform as specified in any test, repair or replace the equipment or module to correct the problem. If you have any question, contact our Customer Service Department.

⚠CAUTION

- **All tests should be performed by qualified service personnel only.**
- **Service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**

5.1.1 Testing Tool

See the following sections.

5.1.2 Test Report

Upon the completion of the tests, the table of preventative maintenance test reports and the table of maintenance test reports in this chapter should be kept properly.

5.1.3 Preventative Maintenance

Below are preventative maintenance tests which need to be performed on the equipment. See the following sections for detailed maintenance procedures.

5.1.4 Recommended Frequency

Check/Maintenance Item		Frequency
Visual inspection		1. When first installed or reinstalled.
Power-on test		1. When first installed or reinstalled. 2. Following any repairs or replacement of any main unit parts.
ECG test	Performance Test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. At least once per year.
	Module Calibration	
Electric safety tests	Refer to ***A Electrical Safety Inspection***	1. Following any repair or replacement 2. After the equipment drops. 3. At least once every two years.
Recorder check		Following any repair or replacement of the recorder.
Battery check	Functional test	1. When first installed. 2. Whenever the battery is replaced.
	Performance test	Once per year, or if the battery run time reduced significantly.

5.2 Visual Inspection

Inspect the equipment for obvious signs of damage. The test is passed if the equipment has no obvious signs of damage. Follow these guidelines when inspecting the equipment:

- Carefully inspect the case, display screen, and keys for obvious signs of damage.
- Inspect the power cord, wall mount, and accessories for obvious signs of damage.
- Inspect all external connections for loose connectors, bent pins or frayed cables.
- Inspect all connectors on the equipment for loose connectors or bent pins.
- Make sure that safety labels and data plates on the equipment are clearly legible.

5.3 Power-on Test

This test is to verify that the equipment can power up correctly. The test is passed if the equipment starts up by following this procedure:

1. Install the battery, and connect the equipment to AC power. The AC mains indicator and battery indicator are illuminated.
2. Press the Power switch to turn on the equipment.

The equipment performs self-test when the equipment is powered on. Corresponding message pops up if any problem is detected during power-on.

5.4 ECG Performance Test

Tool required:

- Patient simulator, Medsim300B or equivalent equipment

Test Method:

1. Connect the patient cable to the equipment under test and the lead wires to the patient simulator.
2. Set the patient simulator as follows: ECG sinus rhythm, HR = 80 bpm, with the amplitude as 1 mV (default setting).
3. Check that the displayed ECG waveforms are clear and complete without obvious noise.
4. Press the ECG key to start automatic ECG measurement. Print out the waveforms and diagnosis.
5. Check that the displayed ECG waveforms are clear and complete with the amplitude of lead II waveform about 10 mm (assumed the Gain is set to 10mm/mV), and diagnosis indicating sinus rhythm and HR 80 bpm.
6. Disconnect each of the leads in turn and observe the corresponding lead off message displayed on the screen.

5.5 Battery Check

Tool required:

- None

Functional Test

1. If the equipment is installed with a battery, remove the battery first.
2. Verify that the equipment works correctly when running powered form the AC mains.
3. Remove the AC power cord and install the battery.
4. Turn on the equipment and verify that the equipment still works correctly.

Performance Test

To check the performance of a battery:

1. Disconnect the equipment from the patient.
2. Connect the equipment to the AC mains. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.
3. Disconnect the AC mains and allow the equipment to run from the battery until it shuts off.
4. Verify battery operating time meets the product specification.

5.6 Factory Maintenance

The equipment provides the Factory Maintenance mode for you to check the equipment conveniently. To enter the Factory Maintenance mode:

1. Press the Setup key on the front panel to enter the main menu.
2. Select [**Maintenance**] and enter the password.
3. Select [**Factory Maintenance**] and enter the password.

   Then the equipment automatically restarts to enter the Factory Maintenance mode.

In the Factory Maintenance mode, you can perform the following tests:

- Display test
- Sound test
- Keypad test
- Lead wire check
- Recorder test
- Internal communication test
- USB test
- Internal storage test
- Barcode reader test

To perform a test, select the desired item and follow the on-screen prompt.

In the Factory Maintenance mode, you can also

- View device information
- Configure the equipment
- Check work log
- Format the internal memory
- Input the equipment's serial number
- Debug the equipment

To exit the maintenance mode, turn off the equipment.

5.7 Electrical Safety Tests

Refer to ***A Electrical Safety Inspection***.

Maintenance and Test Report

(See the above sections for detailed test procedures and contents)

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	**Model/No.**	**Expiration Date for Calibration**

Test Contents	**Test Record**	**Test Result (Pass/Fail)**
Visual Inspection		
The housing, display screen, keys, power cord, and accessories have no obvious signs of damage.		
The external connecting cables are not frayed and the connector pins are not loose and bent.		
The external connectors are not loose or their pins are not bent.		
The safety labels and data plate are clearly legible.		
Power-on Test		
The power-on self test is passed. The power indicator works correctly and the equipment starts up properly.		
Performance test		

ECG performance test and calibration		
The ECG waveforms displayed and printed out should be clear and complete without obvious noise. The amplitude of lead II waveform is about 10 mm and diagnosis indicate sinus rhythm and HR 80 bpm.		
ECG Lead Off prompt behaves correctly.		
Recorder check		
The recorder can print ECG waves correctly and the printout is clear.		
Simulate recorder problems, such as out of paper and paper jam, the message "Check Recorder" shall be presented.		
Battery Check		
The equipment can operates correctly from battery power when an AC power failure accidentally occurs.		
The equipment can operate independently on a single battery.		

Test conclusion:

Tested by: _____ **Test date:** _____

6 Troubleshooting

6.1 Overview

In this chapter, equipment problems are listed along with possible causes and recommended corrective actions. Refer to the tables to check the equipment, identify and eliminate the troubles.

The troubles we list here are frequently arisen difficulties and the actions we recommend can correct most problems, but not all of them. For more information on troubleshooting, contact our Customer Service Department.

6.2 Parts Replacement

The equipment's PCBs, major parts and components are replaceable. Once you isolate a PCB you suspect defective, follow the instructions in Chapter ***7 Disassembly and Repair t***o replace the PCB with a known good one and check that the trouble disappears or the equipment passes all performance tests. Defective PCB can be sent to us for repair. If the trouble remains, exchange the replacement PCB with the original suspicious PCB and continue troubleshooting as directed in this chapter.

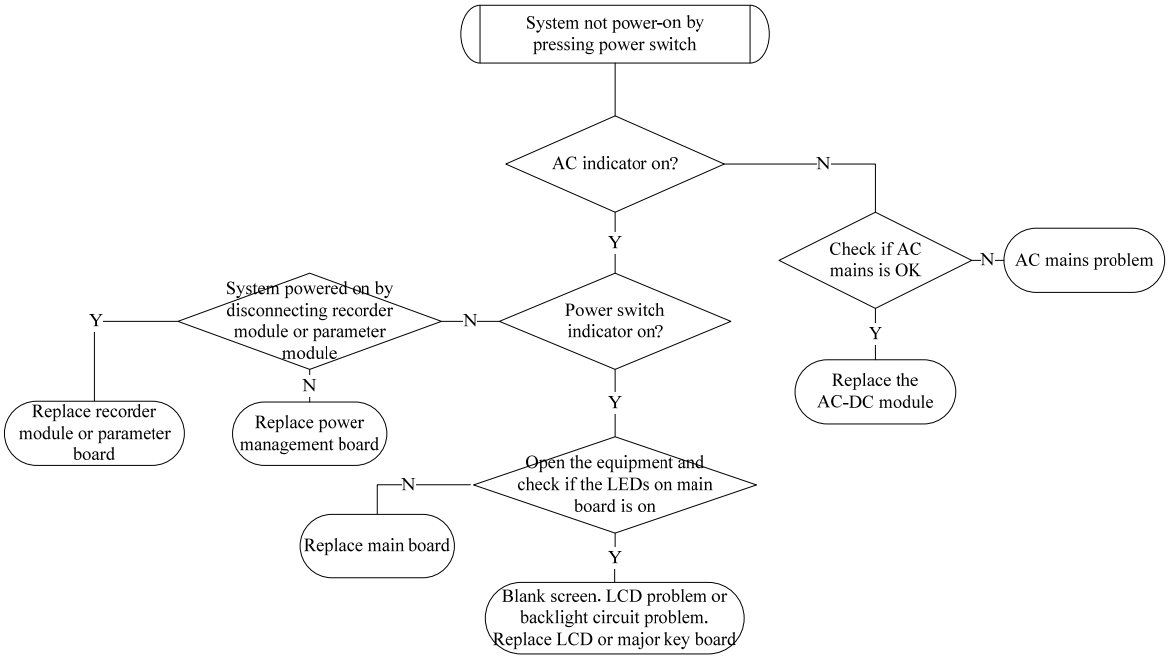
To obtain information on replacement parts or order them, refer to ***9 Replaceable Parts and Upgrade Packages.***

6.3 General Problems and Prompts

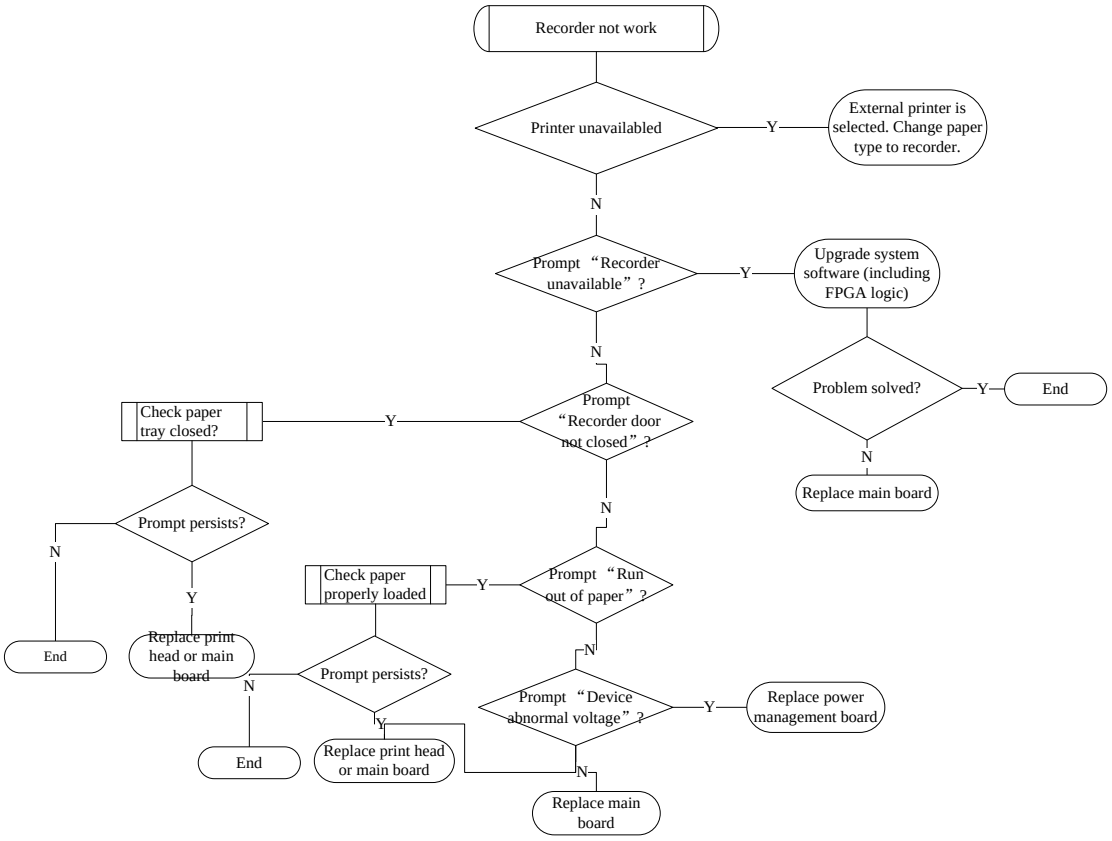
Refer to ***Chapter 9 Troubleshooting*** of the equipment's operating manual.

6.4 Troubleshooting Guide

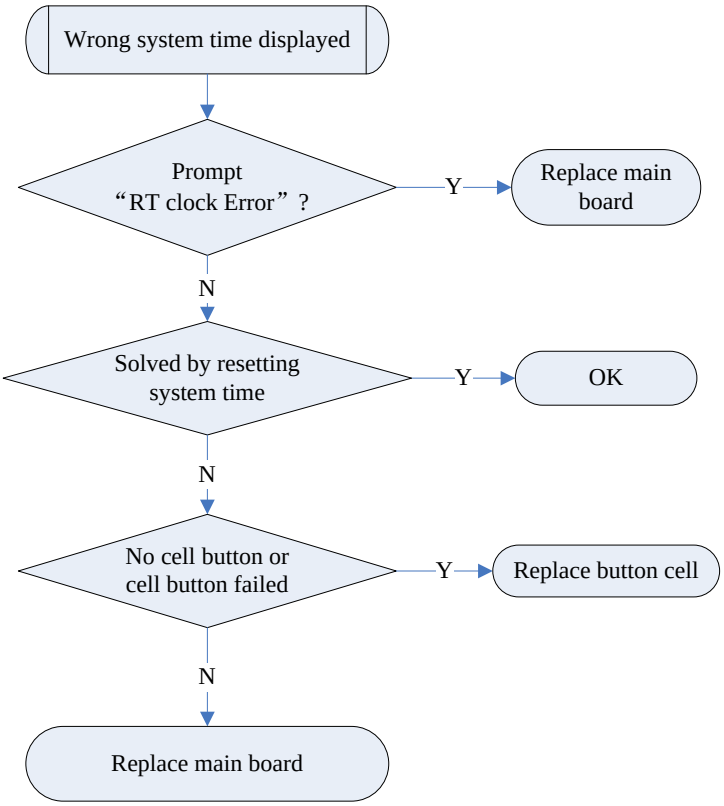
6.4.1 Power On/Off Failure


System not power-on by pressing power switch
AC indicator on?
N
Y
Check if AC mains is OK
N
AC mains problem
Y
Replace the AC-DC module
Power switch indicator on?
N
System powered on by disconnecting recorder module or parameter module
Y
N
Replace recorder module or parameter board
Replace power management board
Y
Open the equipment and check if the LEDs on main board is on
N
Replace main board
Y
Blank screen. LCD problem or backlight circuit problem. Replace LCD or major key board

6.4.2 Recorder Failure



6.4.3 Wrong System Time



FOR YOUR NOTES

7 Disassembly and Repair

7.1 Tools Required

To disassemble and replace the parts and components, the following tools may be required:

- Philips screwdrivers
- Tweezers
- Sharp nose pliers
- Clamp

7.2 Preparations for Disassembly

Before disassembling the equipment, finish the following preparations:

- Stop measuring, turn off the equipment, and disconnect all the accessories and peripheral devices.
- Disconnect the AC power source and remove the battery.

⚠ WARNING

- **All the operations should be performed by qualified service personnel only.**
- **Before disassembling the equipment, be sure to eliminate the static charges first. When disassembling the parts labeled with static-sensitive symbols, make sure you are wearing electrostatic discharge protection such as antistatic wristband or gloves to avoid damaging the equipment.**
- **Follow correct sequence to disassembly the equipment. Otherwise, the equipment may be damaged permanently.**
- **Be sure to disconnect all the cables before disassembling any parts. Be sure not to damage any cables or connectors.**
- **Place the screws and parts from the same module together to facilitate reassembling.**
- **Be sure to place removed screws and disassembled parts properly, preventing them from being lost or contaminated.**
- **To reassemble the equipment, first assemble the assemblies, and then the main unit. Carefully route the cables.**
- **Properly connect and route the cables and wires when reassembling the equipment to avoid short circuit.**
- **Select appropriate screws to assemble the equipment. If unfit screws are tightened by force, the equipment may be damaged and the screws or part may fall off during use, causing unpredictable equipment damage or human injury.**

7.3 Disassembling the Main Unit

To disassemble the equipment, place the equipment on a work bench free from foreign material, avoiding damaging the screen.

7.3.1 Removing the Battery

1. Disconnect the AC mains. Lay the equipment on the work bench. Unscrew the M3×6 screw that secures the battery door.
2. Remove the battery.

7.3.2 Removing Bottom Case Assembly

1. Pull out the paper tray to the extent as shown below.
2. Unscrew the seven M4X10 screws and remove the bottom case assembly.

The bottom case assembly consists of 5 replaceable parts:

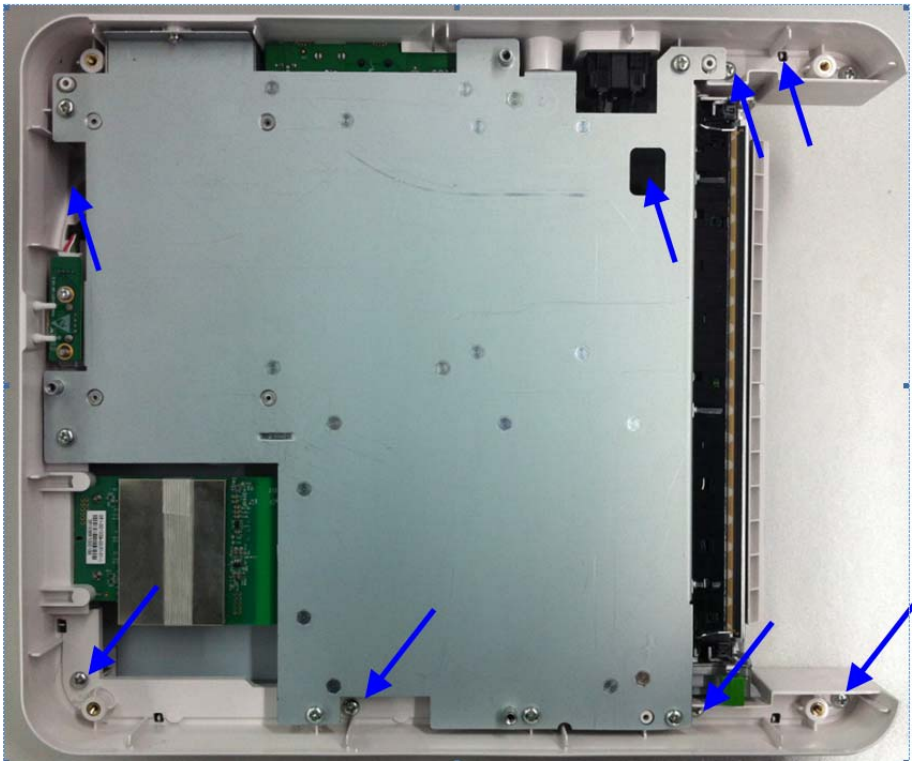
115-022838-00	Bottom case FRU
115-022839-00	Recorder door FRU
043-003531-00	Paper tray top cover
043-003532-00	Spacer bar
115-022972-00	Paper tray FRU, with label instructing paper loading

7.3.3 Removing the Top Cover FRU

1. Unscrew the eight M4×10 screwing securing the top cover assembly.
2. Disconnect the cable connecting the main board and the button board.
3. Remove the top cover FRU.

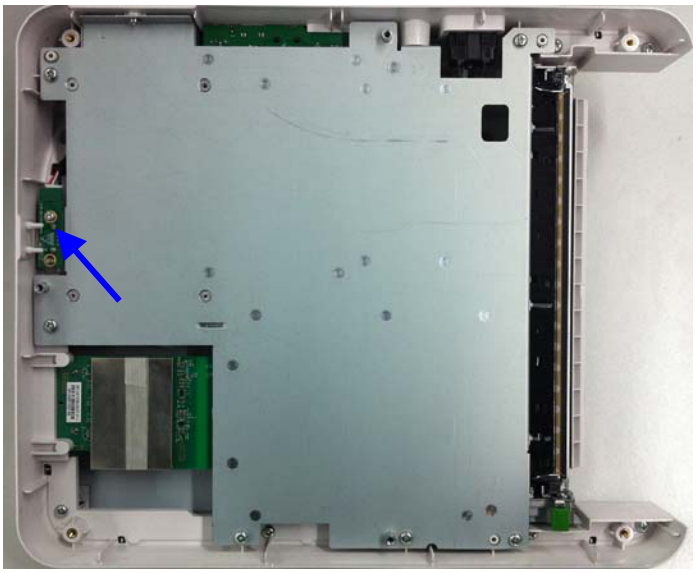
Note

- **You do not need to remove any screws securing the main plate hold (FTP) when removing the top cover FRU.**



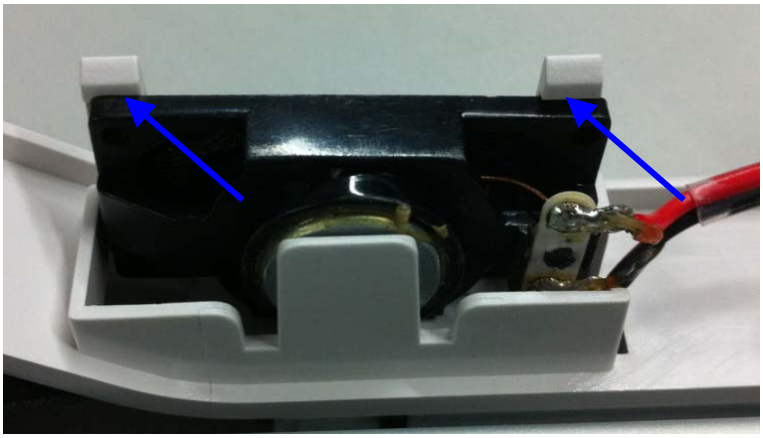
7.3.4 Removing the M502 USB Interface PCBA

After removing the top cover assembly, unscrew the M3×6 screw. Then you can remove the M502 USB interface PCBA.



7.3.5 Removing the Speaker

Release the two clips, and then remove the speaker.

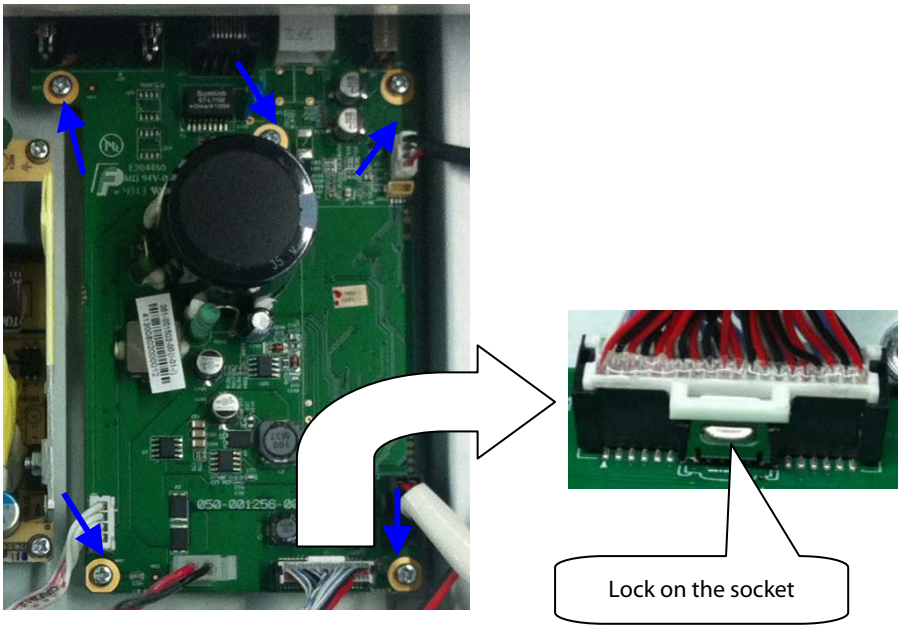


7.3.6 Removing the AC-DC Module

Unscrew the four M3×6 screws to remove the power supply board (16V, 63 W).

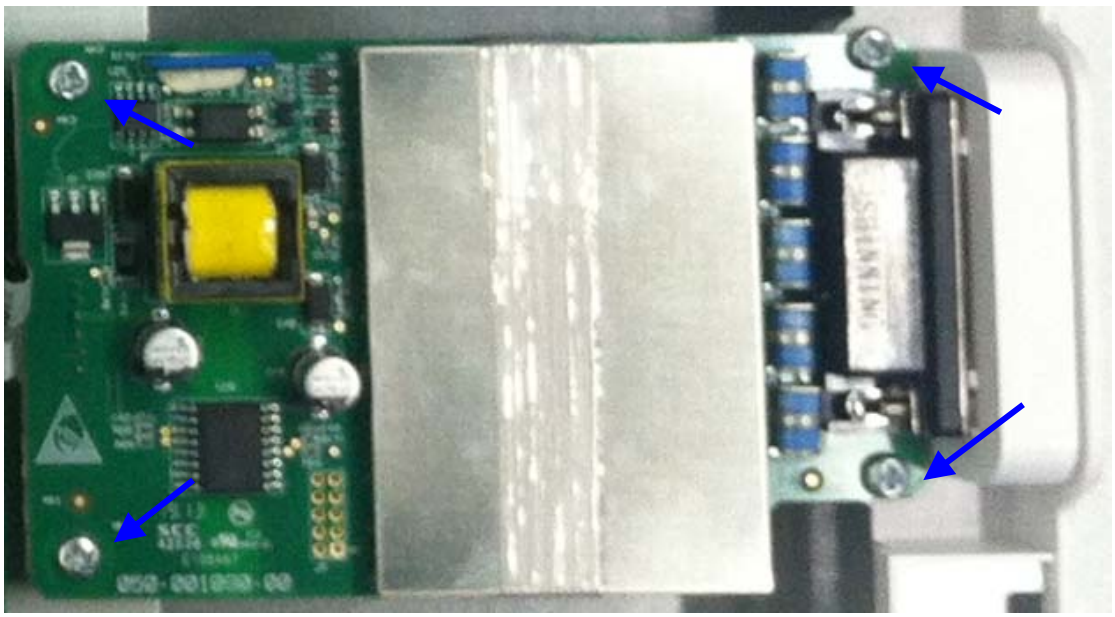
7.3.7 Removing the Power Management and Interface Board PCBA

1. Unscrew the five M3×6 screws.
2. Remove the power management and interface board PCBA.
3. Press down the lock on the socket and carefully disconnect the cable connecting the main board and the power management board.



7.3.8 Removing the ECG Board (FRU)

1. Unscrew the four M3×6 screws.
2. Remove the ECG board PCBA (FRU).



7.3.9 Removing the Battery Interface Board PCBA

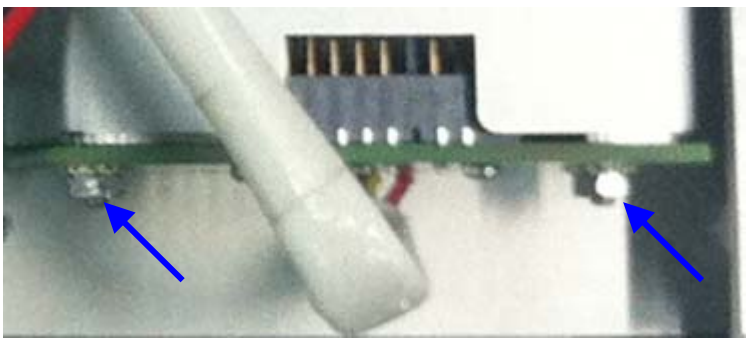
1. Unscrew the two M3 nuts.
2. Remove the battery interface board PCBA.

When reassemble the battery interface board PCBA:

1. Place the battery in the battery compartment.
2. Check that the battery properly connects with the battery interface board.
3. Tight the two M3 nuts.
4. Take out the battery.

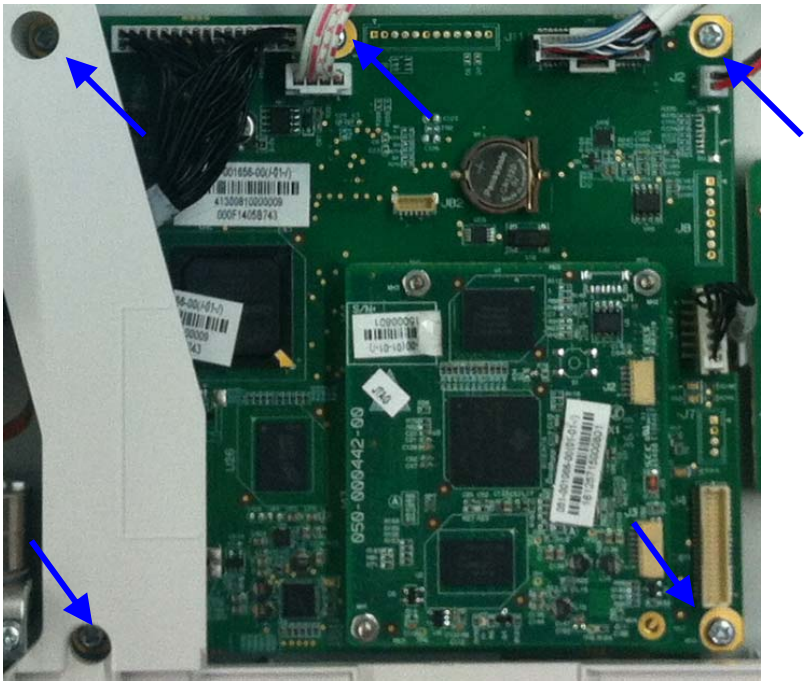
NOTE

- **Do not allow metal parts to touch the welding point during removing and reassemling the battery interface board.**



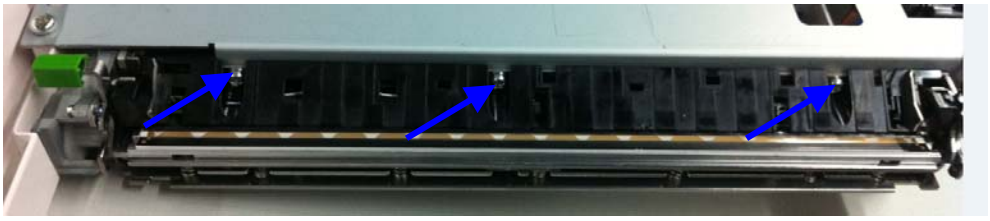
7.3.10 Removing the Main Board FRU

1. Unscrew the five M3×6 screws.
2. Remove the main board FRU.



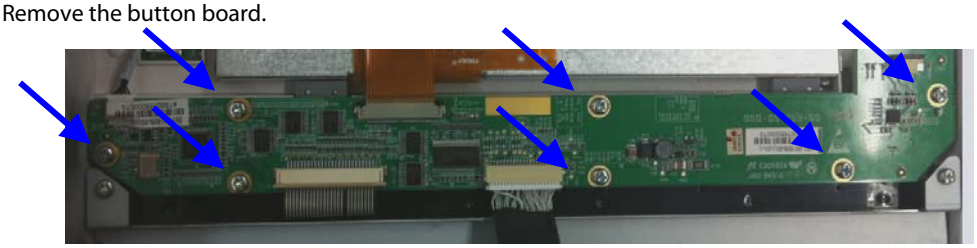
7.3.11 Removing the Thermal Print Head

1. Unscrew the three M3×6 screws.
2. Remove the thermal print head.



7.3.12 Removing the Button Board

1. Unscrew the seven PT3×8 tapping screws.
2. Remove the button board.



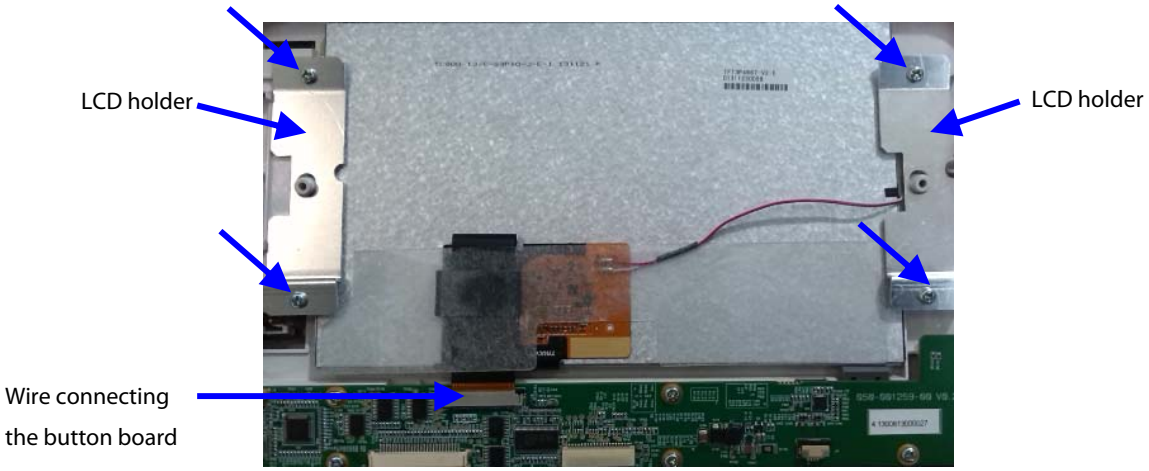
7.3.13 Replacing the Power Button and Function Buttons

You can replace the power button and function buttons after removing the button board.拆

7.3.14 Removing the LCD

1. Unscrew the four PT3×8 tapping screws.
2. Disconnect the wire connecting the button board.
3. Remove the LCD holder.
4. Remove the LCD.

Remove the LCD.



7.3.15 Removing the Top Cover FRU

The top cover FRU does not include the LCD assembly, button board, and keyboard holder.

The top cover FRU has the following configurations:

115-022830-00	Top cover FRU (R12 lens)
115-022831-00	Top cover FRU (R12 touchscreen)
115-022832-00	Top cover FRU (R12A lens)
115-022833-00	Top cover FRU (R12A touchscreen)

The top cover FRU for the equipment configured with the touchscreen consists the following parts:

- Top cover (R12 mark or R12A mark)
- Keyboard
- Touchscreen (R12 orR12A)

The top cover FRU for the equipment not configured with the touchscreen consists the following parts:

- Top cover (R12 mark or R12A mark)
- Keyboard
- Lens (R12 orR12A)
- Touch keypad board

8 Parts

8.1 Introduction

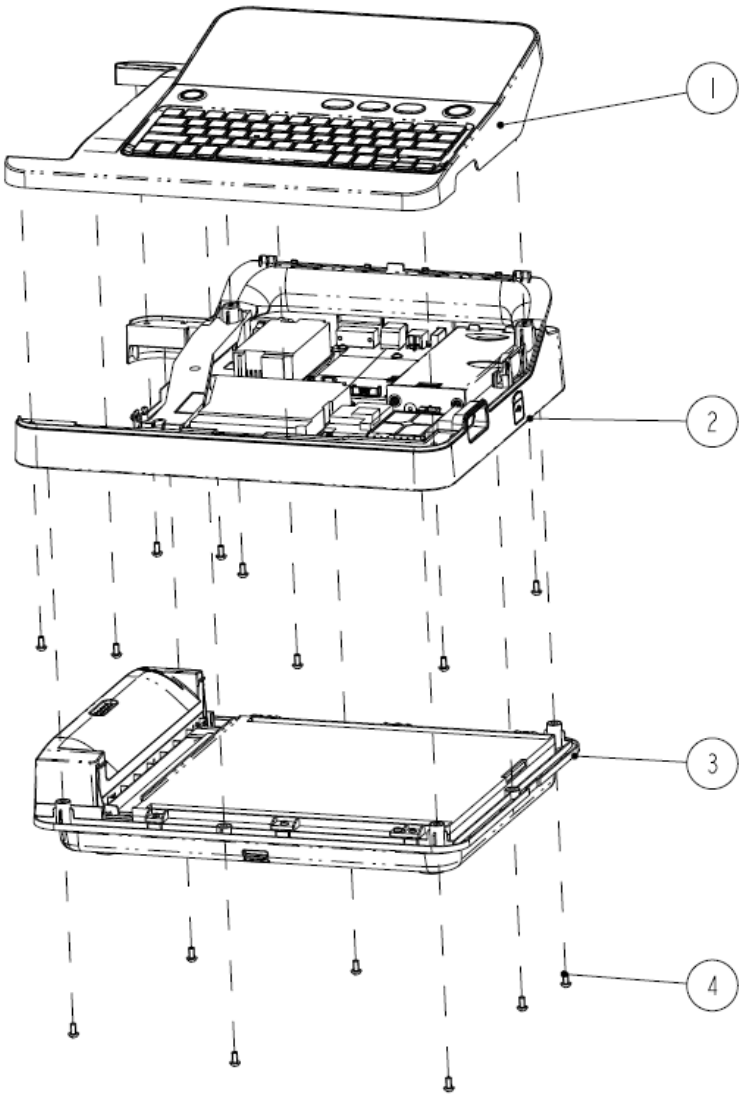
This chapter contains the exploded views and parts lists of the main unit. It helps the engineer to identify the parts during disassembling the equipment and replacing the parts. This manual is based on the maximum configuration. Your equipment may not have same parts and the quantity of the screws or stacking sleeves etc. may be different with those included in the parts lists.

NOTE

- **The part number listed in the Parts List is only for checking the FRU part number which is also included in the Parts List. Please provide the FRU parts number if you want to purchase the spare parts.**

8.2 Main Unit

8.2.1 Exploded View

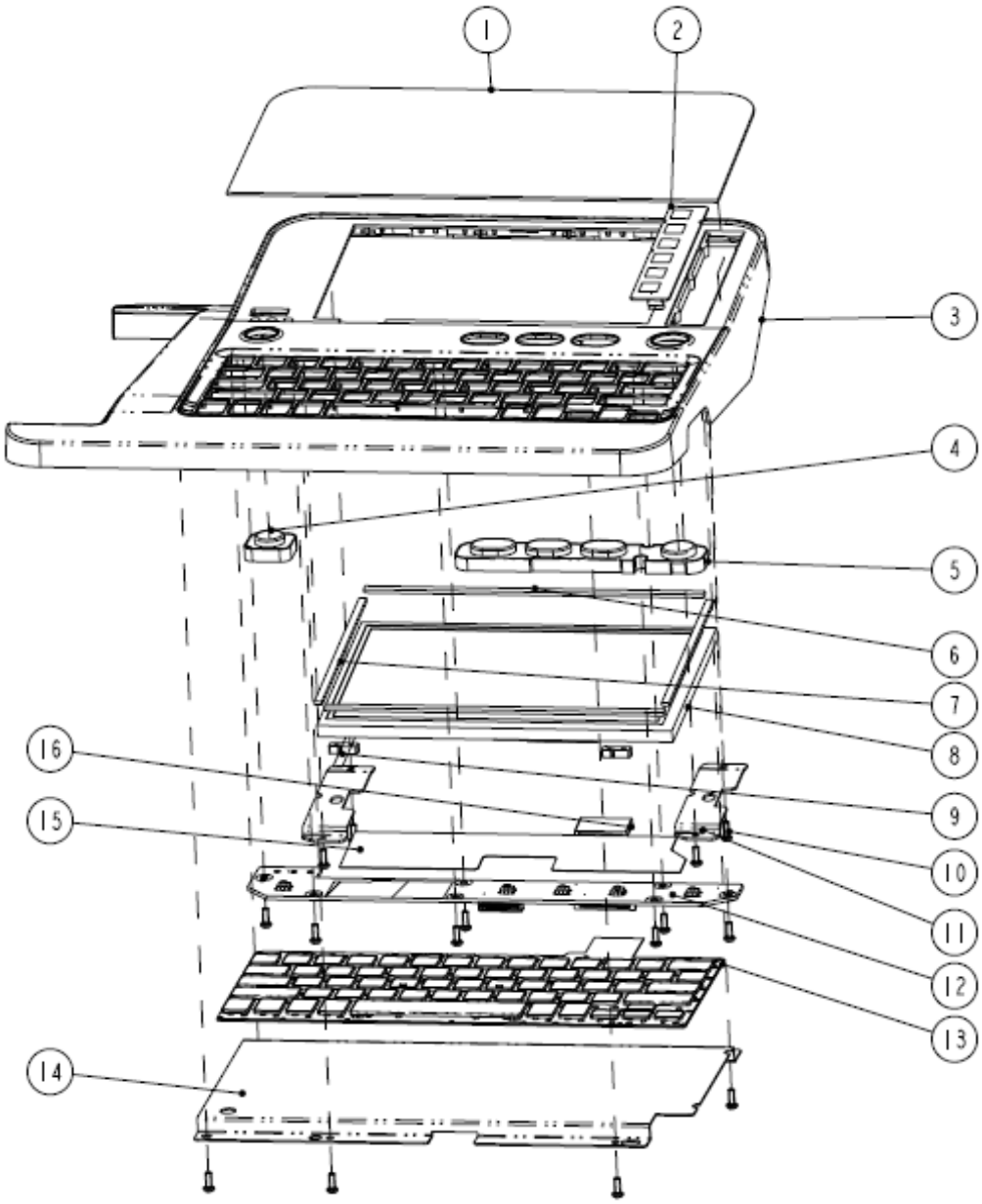


8.2.2 Parts List

SN	PN	Description
1	/	Top cover assembly
2	/	Middle panel assembly
3	/	Bottom case assembly
4	/	Cross pan head screw, GB/T818-2000 M4×8

8.3 Upper Housing Assembly

8.3.1 Exploded View



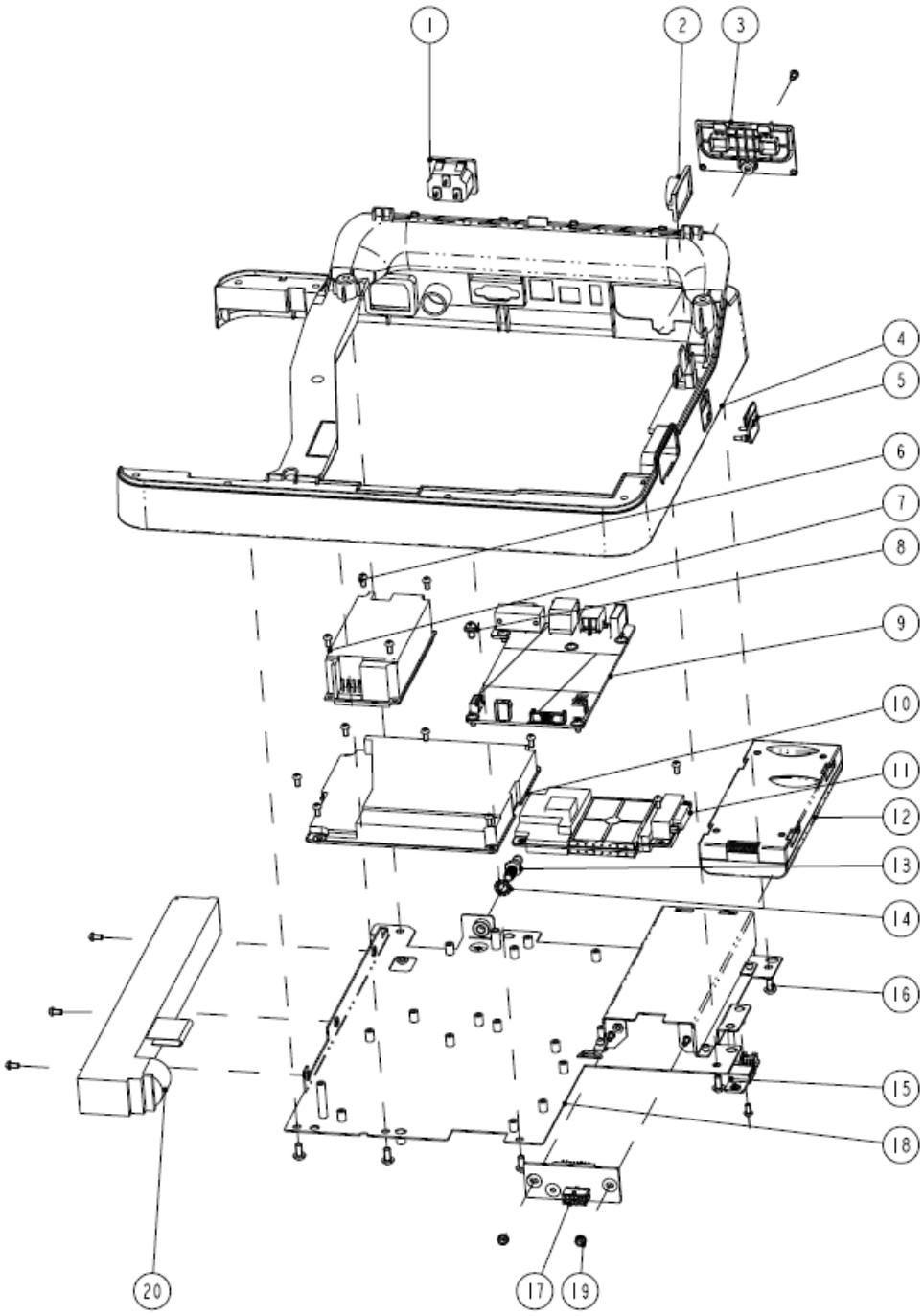
8.3.2 Parts List

	PN	Description	FRU part number	Remarks
1	/	Lens	115-023370-00	Lens and touch keypad board FRU, for R12
			115-023371-00	Lens and touch keypad board FRU, for R12A
		Touchscreen	021-000132-00	For R12
			021-000140-00	For R12A

	PN	Description	FRU part number	Remarks
2	/	Touch keypad board (only for the machine not configured with touchscreen)	115-023370-00	Lens and touch keypad board FRU, for R12
			115-023371-00	Lens and touch keypad board FRU, for R12A
3	/	Top cover	115-022830-00	Top cover FRU (R12 lens), used when keyboard or top cover needs to be replaced.
			115-022832-00	Top cover FRU (R12A lens), used when keyboard or top cover needs to be replaced.
			115-022831-00	Top cover FRU (R12 touchscreen), used when keyboard or top cover needs to be replaced.
			115-022833-00	Top cover FRU (R12A touchscreen), used when keyboard or top cover needs to be replaced.
4	049-000600-00	Power key	049-000600-00	/
5	049-000601-00	Main function keys	049-000601-00	/
6	/	LCD dust-proof, long	/	/
7	/	LCD dust-proof, short	/	/
8	021-000130-00	LCD, 8-inch	115-022834-00	LCD FRU
9	049-000635-00	LCD limit block	049-000635-00	/
10	M04-003105---	Cross pan head tapping screw, PT3×8	/	/
11	/	LCD securing plate	/	/
12	051-001505-00M502	Major button board	051-001505-00M502	/
13	/	Keyboard	115-022830-00	Top cover FRU (R12 lens), used when keyboard or top cover needs to be replaced.
			115-022832-00	Top cover FRU (R12A lens), used when keyboard or top cover needs to be replaced.
			115-022831-00	Top cover FRU (R12 touchscreen), used when keyboard or top cover needs to be replaced.
			115-022833-00	Top cover FRU (R12A touchscreen), used when keyboard or top cover needs to be replaced.
14	042-009257-00	Keyboard holder	/	/
15	/	Magnetic ring holder	/	/
16	/	Magnetic ring, CORE, 28(24)*15*3.5(0.75) mm , Flat ferrite	/	/

8.4 Middle Frame Assembly（115-022702-00）

8.4.1 Exploded View



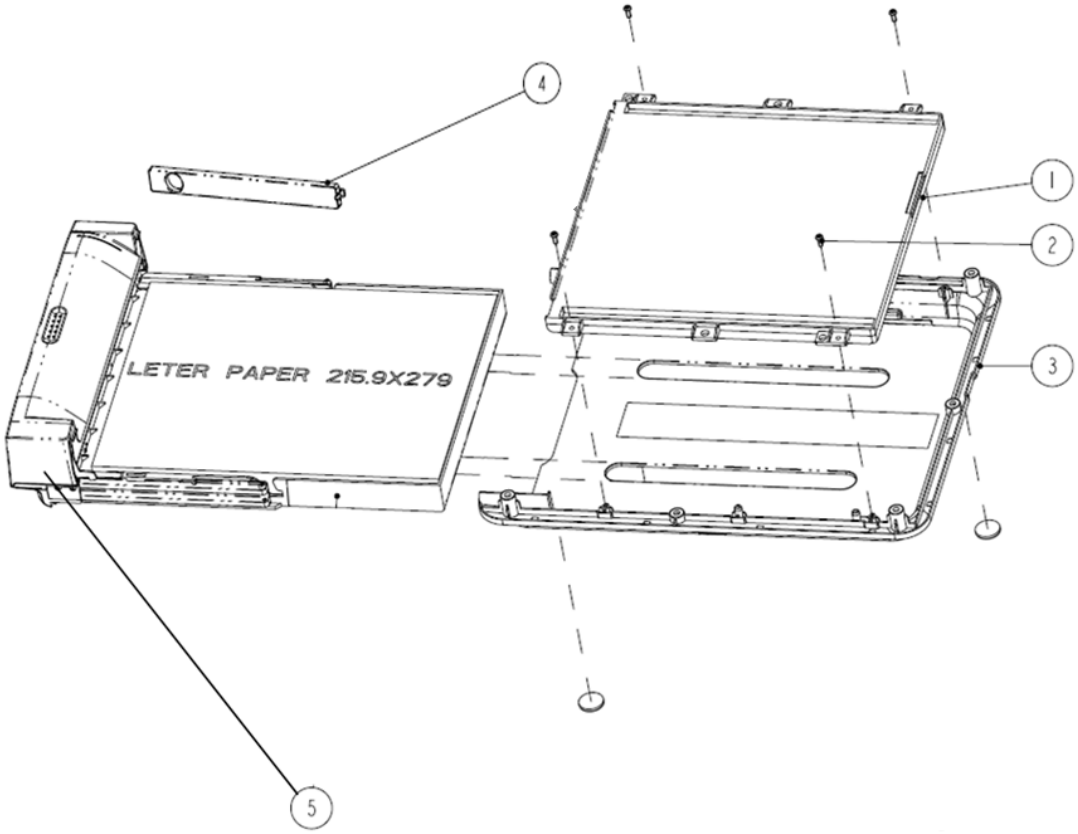
8.4.2 Parts List

	PN	Description	FRU part number	Remarks
1	009-003818-00	AC input receptacle cable	009-003818-00	/
2	020-000015-00	Speaker, 2W, 4ohm, 60mm	020-000015-00	/
3	043-003530-00	Battery door	043-003530-00	/
4	043-003525-00	Middle frame	043-003525-00	/

	PN	Description	FRU part number	Remarks
5	049-000591-00	USB plug (white)	049-000591-00	/
6	M04-002505---	Cross pan head screw	/	/
7	022-000159-00	AC-DC module, 15V, 63W	022-000159-00	/
8	M04-051141---	Cross pan head screw kit, M4×8	/	/
9	051-001502-00	M502 power management and interface board PCBA (standard)	051-001502-00	/
10	/	Main board PCBA	115-022978-00	Main board FRU, standard configuration
			115-022837-00	Main board FRU, full configuration
			115-022981-00	Main board FRU, standard configuration, with Glasgow algorithm
			115-022836-00	Main board FRU, full configuration, with Glasgow algorithm
			115-022989-00	Main board FRU, standard configuration, with PDF software
			115-022988-00	Main board FRU, full configuration, with PDF software
			115-022980-00	Main board FRU, standard configuration, with Glasgow algorithm and PDF software
			115-022835-00	Main board FRU, full configuration, with Glasgow and PDF
11	051-001339-00	ECG board PCBA	051-001339-00	/
12	M05-010002-06	Lithium battery, 11.1V, 4500mAh	M05-010002-06	/
13	/	Equipotential grounding terminal	/	/
14	/	Lock washer	/	/
15	051-001503-00	M502 USB interface board PCBA	051-001503-00	/
16	M04-051001-00	Cross pan head screw, M4×8	/	/
17	051-001460-00	Battery interface board PCBA	/	/
18	/	Main plate holder	/	/
19	M04-011002---	Nut & lock washer kit, M3	/	/
20	024-000534-00	Thermal print head, 216mm	024-000534-00	/

8.5 Bottom Case Assembly（115-022703-00）

8.5.1 Exploded View



8.5.2 Parts List

	PN	Description	FRU part number	Remarks
1	043-003531-00	Paper tray top cover	043-003531-00	/
2	M04-003105---	Cross head topping screw,PT3×8	/	/
3	043-003526-00	Bottom case	043-003526-00	/
4	043-003532-00	Spacer bar	043-003532-00	/
5	115-022839-00	Recorder door FRU	115-022839-00	/

FOR YOUR NOTES

9 Replaceable Parts and Upgrade Packages

9.1 Replaceable Parts and Upgrade Packages

	Part Number	Description
1.	115-022978-00	Main board FRU, standard configuration
2.	115-022837-00	Main board FRU, full configuration
3.	115-022981-00	Main board FRU, standard configuration, with Glasgow algorithm
4.	115-022836-00	Main board FRU, full configuration, with Glasgow algorithm
5.	115-022989-00	Main board FRU, standard configuration, with PDF software
6.	115-022988-00	Main board FRU, full configuration, with PDF software
7.	115-022980-00	Main board FRU, standard configuration, with Glasgow algorithm and PDF software
8.	115-022835-00	Main board FRU, full configuration, with Glasgow and PDF
9.	022-000159-00	AC-DC module, 15V 63W
10.	009-003818-00	AC input receptacle and cable
11.	115-018611-00	ECG board PCBA (FRU)
12.	115-023491-00	WIFI module kit
13.	020-000014-01	Speaker, 2W, 4ohm, 500Hz
14.	051-001502-00	M502 power management and interface board PCBA (standard)
15.	051-001460-00	Battery interface board PCBA
16.	051-001503-00	M502 USB interface board PCBA
17.	051-001505-00	M502 major button board PCBA
18.	115-022834-00	LCD FRU
19.	024-000534-00	Thermal print head, 216mm
20.	115-018012-00	Lithium battery, 11.1 V, 4500 mAh, LI23S002A
21.	M05-010R03---	Button cell, lithium 3V, 35mAh D12.5*2.0
22.	043-004288-00	Middle frame
23.	043-004290-00	Battery door
24.	049-000514-00	USB plug
25.	115-023370-00	Lens and touch keypad board FRU (R12)
26.	115-022830-00	Top cover FRU (R12 lens)
27.	115-023371-00	Lens and touch keypad board FRU, for R12A
28.	115-022832-00	Top cover FRU (R12A lens)
29.	021-000132-00	Touchscreen (R12)
30.	115-022831-00	Top cover FRU (R12 touchscreen)
31.	021-000140-00	Touchscreen (R12A)
32.	115-022833-00	Top cover FRU (R12A touchscreen)
33.	049-000635-00	LCD limit block

	Part Number	Description
34.	049-000642-00	Power supply button (M502 silk print)
35.	049-000643-00	Function buttons (M502, Chinese)
36.	049-000644-00	Function buttons (M502, English)
37.	043-003531-00	Paper tray top cover
38.	043-003532-00	Spacer bar
39.	115-022838-00	Bottom case FRU
40.	115-022839-00	Recorder door FRU
41.	115-022972-00	Paper tray FRU, with label instructing paper loading
42.	009-003237-00	Cable, connecting the power management board and the AC-DC module
43.	009-003325-00	Cable, connecting the main board and the ECG board
44.	009-003727-00	Cable, connecting the main board to the button board
45.	009-003728-00	Cable, connecting the main board and the power management board
46.	009-003729-00	Cable, connecting the main board and the 24 VDC on the power management board
47.	009-003730-00	Cable, connecting the power management and interface board and the USB interface board
48.	009-003731-00	Cable, connecting the major button board and the function button board
49.	009-004051-00	Cable, connecting the main board and thermal module
50.	115-022979-00	Wi-Fi upgrade package
51.	115-022827-00	PDF software upgrade package
52.	115-022828-00	Glasgow upgrade package (English)
53.	115-022829-00	Glasgow upgrade package (Chinese)

9.2 Parts Change List

Not applicable.

A Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe, such as Fluke, Metron, or Gerb, may require modifications to the procedure. Please follow the instructions of the analyzer manufacturer.

The consistent use of a safety analyzer as a routine step in closing a repair or upgrade is emphasized as a mandatory step if an approved agency status is to be maintained. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

A.1 Power Cord Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

A.2 Device Enclosure and Accessories

A.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

A.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

A.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

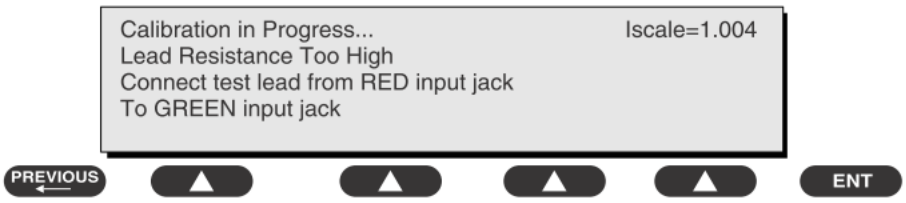
A.4 Protective Earth Resistance

Protective Earth Resistance is measured using the RED test lead attached to the DUT Protective Earth terminal or enclosure. Select the test current by pressing SOFT KEY 3 to toggle 25AMP. The front panel outlet power is turned off for this test.

The following conditions apply: L1 and L2 Open.

Preparation

1. First select the test current that will be used for performing the Protective Earth Resistance test by pressing AMPERES (SOFT KEY 3).
2. Connect the test lead(s) between the RED input jack and the GREEN input jack.
3. Press CAL LEADS. The 601PRO will measure the lead resistance, and if less than 0.150 Ohms, it will store the reading and subtract it from all earth resistance readings taken at the calibrated current.



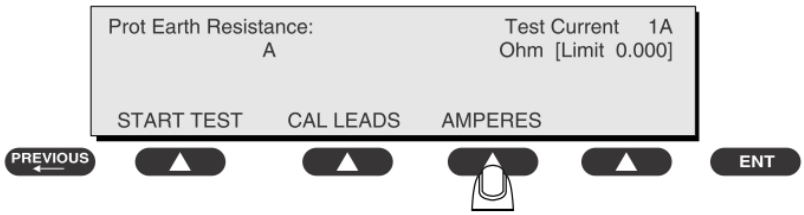
If the calibration fails, the previously stored readings will be used until a passing calibration has occurred.

⚠WARNING

- **During Earth Resistance testing, the DUT must be plugged into the 601PRO front outlet. If the DUT fails Earth Resistance, discontinue tests and label the device defective.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet.
2. Attach the 601PRO RED input lead to the device's Protective Earth terminal or an exposed metal area.
3. Press shortcut key 3. The Protective Earth Resistance test is displayed.
4. Press SOFT KEY 3 to select a test current (25AMP). The selected test current is displayed in the upper right corner of the display.



5. Press START TEST to start the test. The test current is applied while resistance and current readings are taken. This takes approximately 5 seconds.
6. Press the print data key at any time to generate a printout of the latest measurement(s).

NOTE

- **When "Over" is displayed for Ohms, this signifies that a valid measurement was not obtained because either an open connection was detected or that the measurement was not within range. Readings greater than 9.999 Ohms will be displayed as Over.**

In Case of Failure

Once it reaches the limitation, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

ALL COUNTRIES R = 0.2 Ω Maximum

A.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

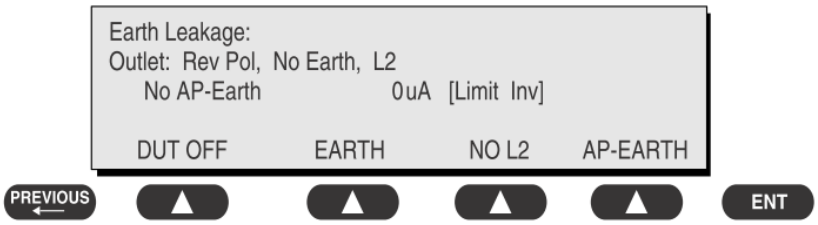
Leakage current is measured the following ways:

- Earth Leakage Current, leakage current measured through DUT outlet Earth
- Earth Leakage Current AP-EARTH (ALL Applied Parts connected to Earth), leakage current measured through DUT outlet Earth

There is no need to attach a test lead; the 601PRO automatically connects the measuring device internally.

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the device's applied parts to the 601PRO applied part terminals if applicable.
3. Press shortcut key 4.The Earth Leakage test appears on the display, and the test begins immediately:



- SOFT KEY 1 toggles the DUT outlet Polarity from Normal to Off to Reverse.
- SOFT KEY 2 toggles the DUT outlet from Earth to No Earth.
- SOFT KEY 3 toggles the DUT outlet from L2 to No L2.
- SOFT KEY 4 toggles the AP to Earth to No AP to Earth.

4. Press the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For UL60601-1,

- 300 μA in Normal Condition
- 1000 μA in Single Fault Condition

For IEC60601-1,

- 500 μA in Normal Condition
- 1000 μA in Single Fault Condition

A.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only response.

Preparation

Perform a calibration from the Mains on Applied Part menu.

The following outlet conditions apply when performing this test:

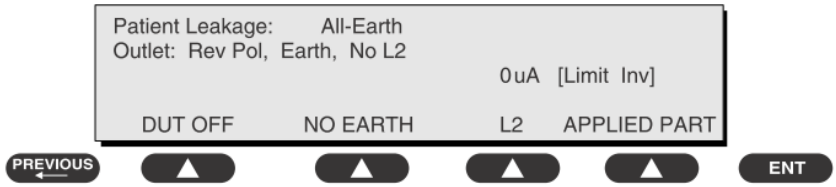
- Normal Polarity, Earth Open, Outlet ON Normal Polarity, Outlet ON
- Normal Polarity, L2 Open, Outlet ON Reversed Polarity, Outlet ON
- Reversed Polarity, Earth Open, Outlet ON Reversed Polarity, L2 Open, Outlet ON

⚠WARNING

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the applied parts to the 601PRO's applied part terminals.
3. Press shortcut key 6. The Patient Leakage test is displayed, and the test begins immediately.



4. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current.
5. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO.
6. Press the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF applied parts

- 10μA in Normal Condition
- 50μA in Single Fault Condition

A.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions as indicated on the display.

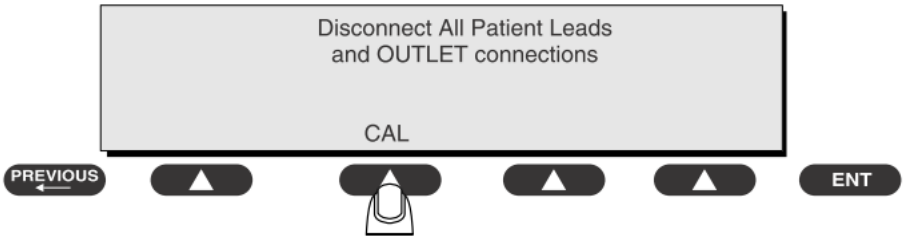
The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

Preparation

To perform a calibration from the Mains on Applied Part test, press CAL (SOFT KEY 2).

1. Disconnect ALL patient leads, test leads, and DUT outlet connections.
2. Press CAL to begin calibration, as shown:



If the calibration fails, the previously stored readings will be used until a passing calibration has occurred. Also, the esc/stop key has no effect during calibration.

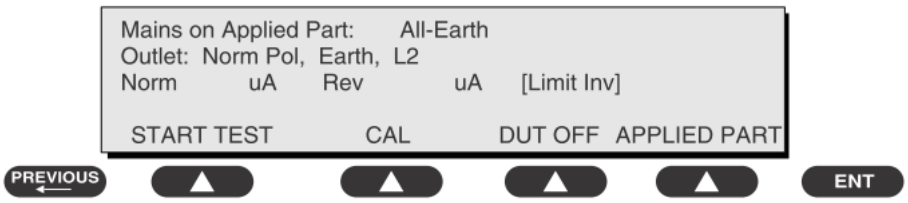
3. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠WARNING

- **A 2-beep-per-second signal indicates high voltage present at the applied part terminals while a calibration is being performed.**
- **High voltage is present at applied part terminals while measurements are being taken.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601
2. Attach the applied parts to the 601PRO applied part terminals.
3. Attach the red terminal lead to a conductive part on the DUT enclosure.
4. Press shortcut key 7. The Mains on Applied Part test is displayed.



5. Select the desired outlet configuration and applied part to test using the appropriate SOFT KEYS:
6. Press START TEST (SOFT KEY 1) to begin the test.
7. Press the print data key to generate a printout of the latest measurement.

NOTE

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

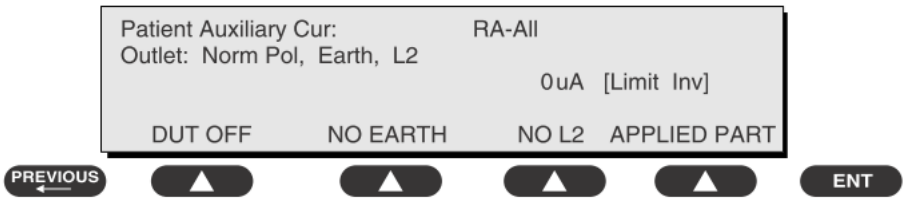
- For CF applied parts: 50 µA

A.8 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected ECG jack and the remaining selected ECG jacks. All measurements may have a true RMS only response.

Preparation

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the patient leads to the 601PRO ECG jacks.
3. Define the Lead Types from the View Settings Option (refer to: Lead Type Definitions in Section 5 of this chapter).
4. Press shortcut key 8. The Patient Auxiliary Current test is displayed, and the test begins immediately. Display values are continuously updated until another test is selected.



5. Press SOFT KEYS 1-4 to select leakage tests
6. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current:
7. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO:
8. Press the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation cannot be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF applied parts,

- 10μA in Normal Condition
- 50μA in Single Fault Condition

A.9 Scheduled Electrical Safety Inspection

For scheduled electrical safety inspection, test items 1, 2, 3, 4, 5, 6, 7, and 8 included in the ***ELECTRICAL SAFETY INSPECTION FORM*** shall be performed.

ELECTRICAL SAFETY INSPECTION FORM

<table>
<tr><td colspan="5">Location:</td><td colspan="2">Technician:</td></tr>
<tr><td colspan="5">Equipment:</td><td colspan="2">Control Number:</td></tr>
<tr><td colspan="3">Manufacturer:</td><td colspan="2">Model:</td><td colspan="2">SN:</td></tr>
<tr><td colspan="5">Measurement equipment /SN:</td><td colspan="2">Date of Calibration:</td></tr>
<tr><td colspan="5">INSPECTION AND TESTING</td><td>Pass/Fail</td><td>Limit</td></tr>
<tr><td>1</td><td colspan="4">Power Cord Plug</td><td></td><td></td></tr>
<tr><td>2</td><td colspan="4">Device Enclosure and Accessories</td><td></td><td></td></tr>
<tr><td>3</td><td colspan="4">Device Labeling</td><td></td><td></td></tr>
<tr><td>4</td><td colspan="3">Protective Earth Resistance</td><td>Ω</td><td></td><td>Max 0.2 Ω</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2">Earth Leakage</td><td>Normal condition (NC)</td><td>____μA</td><td></td><td rowspan="2">Max:
NC: 300μA(refer to UL60601-1) *
NC: 500μA(refer to IEC60601-1) *
SFC: 1000μA</td></tr>
<tr><td>Single Fault condition (SFC)</td><td>____μA</td><td></td></tr>
<tr><td rowspan="4">6</td><td rowspan="4">Patient Leakage Current</td><td rowspan="2">Normal condition (NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="4">Max:
CF applied part:
NC:10μA, SFC: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">Single Fault condition (SFC)</td><td>☐BF____μA</td><td rowspan="2"></td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">7</td><td colspan="2" rowspan="2">Mains on Applied Part Leakage</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="2">Max:
CF applied part: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="4">8</td><td rowspan="4">Patient Auxiliary Current</td><td rowspan="2">Normal condition (NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="4">Max:
CF applied part:
NC:10μA, SFC: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">Single Fault condition (SFC)</td><td>☐BF____μA</td><td rowspan="2"></td></tr>
<tr><td>☐CF____μA</td></tr>
</table>

Note: The equipment sold to the United States shall comply with the requirement of UL60601-1; others shall comply with the requirement of IEC60601-1.

Name/ Signature: _____ Date:_____

A.10 Electrical Safety Inspection after Repair

The following table specifies test items to be performed after the equipment is repaired.

Repair with main unit not disassembled		Test items: 1, 2, 3
Repair with main unit disassembled	When neither power supply PCBA nor patient electrically-connected PCBA is repaired or replaced	Test items: 1, 2, 3, 4
	When power supply PCBA is repaired or replaced	Test items: 1, 2, 3, 4, 5
	When patient electrically-connected PCBA is repaired or replaced	Test items: 1, 2, 3, 4, 6, 7, 8
	When both power supply PCBA and patient electrically-connected PCBA are repaired or replaced	Test items: 1, 2, 3, 4, 5, 6, 7, 8

ELECTRICAL SAFETY INSPECTION FORM

<table>
<tr><td colspan="4">Location:</td><td colspan="2">Technician:</td></tr>
<tr><td colspan="4">Equipment:</td><td colspan="2">Control Number:</td></tr>
<tr><td colspan="3">Manufacturer:</td><td>Model:</td><td colspan="2">SN:</td></tr>
<tr><td colspan="4">Measurement equipment /SN:</td><td colspan="2">Date of Calibration:</td></tr>
<tr><td colspan="4">INSPECTION AND TESTING</td><td>Pass/Fail</td><td>Limit</td></tr>
<tr><td>1</td><td colspan="3">Power Cord Plug</td><td></td><td></td></tr>
<tr><td>2</td><td colspan="3">Device Enclosure and Accessories</td><td></td><td></td></tr>
<tr><td>3</td><td colspan="3">Device Labeling</td><td></td><td></td></tr>
<tr><td>4</td><td colspan="2">Protective Earth Resistance</td><td>Ω</td><td></td><td>Max 0.2 Ω</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2">Earth Leakage</td><td>Normal condition(NC)</td><td>____μA</td><td></td><td rowspan="2">Max:
NC: 300μA(refer to UL60601-1) *
NC: 500μA(refer to IEC60601-1) *
SFC: 1000μA</td></tr>
<tr><td>Single Fault condition(SFC)</td><td>____μA</td><td></td></tr>
<tr><td rowspan="4">6</td><td rowspan="4">Patient Leakage Current</td><td rowspan="2">Normal condition(NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="4">Max:
CF applied part:
NC:10μA, SFC: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">Single Fault condition(SFC)</td><td>☐BF____μA</td><td rowspan="2"></td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">7</td><td colspan="2" rowspan="2">Mains on Applied Part Leakage</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="2">Max:
CF applied part: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="4">8</td><td rowspan="4">Patient Auxiliary Current</td><td rowspan="2">Normal condition(NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="4">Max:
CF applied part:
NC:10μA, SFC: 50μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">Single Fault condition(SFC)</td><td>☐BF____μA</td><td rowspan="2"></td></tr>
<tr><td>☐CF____μA</td></tr>
</table>

Note: The equipment sold to the United States shall comply with the requirement of UL60601-1; others shall comply with the requirement of IEC60601-1.

Name/ Signature: _____ Date:_____

P/N: 046-006011-00（1.0）